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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/057,108

01/25/2002

Geert Plaetinck

D00590.70011.US

1549

23628 7590 02/14/2008
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EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

02/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/057,108	Applicant(s) PLAETINCK ET AL.	
	Examiner DANA SHIN	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,14,17-22,25-27 and 54-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13,14,17-22,25-27 and 54-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/347,311.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-4-2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 1, 2007 has been entered.

Status of Claims

Currently, claims 13-14, 17-22, 25-27, and 54-56 are pending and under examination on the merits.

Response to Arguments

Applicant's arguments with respect to claims 13-29 have been considered but are moot in view of the new ground(s) of rejection. Applicant's arguments filed on November 11, 2007 are directed to previous rejections which are now withdrawn and therefore they do not address the new rejections detailed below in this Office action. Note that all of the pending claims in the instant case have been amended, and therefore, the newly submitted claim amendment has necessitated new grounds of rejections.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/347,311, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instantly claimed invention is directed to methods for down-regulating or reducing the expression of a gene of interest in *C. elegans* comprising feeding dsRNA. However, the disclosure of 09/347,311 does not provide adequate description and enablement for the claimed methods in the manner provided by the first paragraph of 35 U.S.C. 112. The disclosure of 09/347,311 is completely silent about the claimed methods and method steps. Accordingly, the benefit of an earlier filing date is denied, and therefore the instant filing date of January 25, 2002 will be the effective filing date in the instant case. If applicant believes that the claimed invention was adequately described and enabled as set forth by the first paragraph of 35 U.S.C. 112 in 09/347,311, applicant is advised to point out the particulars in response to this Office action.

Claim Objections

Claim 14 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-14, 17-22, 25-26, and 54-56 are rejected under 35 U.S.C. 102(b) and 102(a) as being anticipated by Fire et al. (WO 99/32619 A1, also applicant's citation).

In the event that the claimed invention is determined to be supported by the disclosure of 09/347,311, the aforementioned claims will remain rejected under 35 U.S.C. 102(a).

The claims are drawn to methods for down-regulating gene expression in *C. elegans* by feeding a micro-organism comprising an expression vector having two T7 promoters flanking a DNA sequence, wherein the promoters produce double-stranded RNA in the micro-organism, wherein the micro-organism is *E. coli* bacterium or a yeast cell, wherein the promoters are tissue-specific promoters.

Fire et al. teach a method for down-regulating target gene expression in *C. elegans* comprising feeding a micro-organism containing an expression vector having two T7 promoters flanking a DNA sequence, wherein the promoters produce double-stranded RNA in the *C. elegans*. See Figures 5A-5C. They teach that the micro-organism comprising the expression vector can be any organism including *E. coli* and yeast (pages 7, 12, 26). They teach that the promoters that mediate transcription of the double-stranded RNA in the micro-organism can be tissue-specific (pages 13, 17-18). See also claims 36-38. Accordingly, all claim limitations are taught by Fire et al.

Claims 13-14, 17-22, 25-26, and 54-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (US 6,506,559 B1).

The claims are described above.

Fire et al. teach a method for down-regulating target gene expression in *C. elegans* comprising feeding a micro-organism containing an expression vector having two T7 promoters flanking a DNA sequence, wherein the promoters produce double-stranded RNA in the *C. elegans*. See Figures 5A-5C. They teach that the micro-organism can be *E. coli* or yeast. See columns 8-9, 11-12. They also teach that the promoters can be tissue-specific promoters (e.g.,

root-specific promoters) in place of the two T7 promoters. See columns 11 and 17. Accordingly, all claim limitations are taught by Fire et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-14, 17-22, 25-27, and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. (WO 99/32619) or Fire et al. (US 6,506,559 B1) as applied to claims 30-39, 70-74, and 80-83 above, further in view of Talkad et al. (*Journal of Bacteriology*, 1978, 135:528-541, also applicant's citation).

The claims are drawn to methods for down-regulating gene expression in *C. elegans* by feeding a micro-organism comprising an expression vector having two T7 promoters flanking a

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DNA sequence, wherein the promoters produce double-stranded RNA in the micro-organism, wherein the micro-organism is *E. coli* bacterium or a yeast cell, wherein the *E. coli* is a RNase III negative strain.

Both of the Fire et al. references teach a method for down-regulating target gene expression in *C. elegans* by feeding a micro-organism comprising an expression vector having two T7 promoters flanking a DNA sequence, wherein the promoters produce double-stranded RNA in the organisms. They both teach that the micro-organism can be a bacterium whose strain is BL21/DE3. Neither of the Fire et al. references teaches that the bacterium is *E. coli* is an RNase III negative strain.

Talkad et al. teach *E. coli* strains that are deficient in RNase III. They teach that RNase III cleaves bacteriophage T7 RNAs as well as double-stranded RNAs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the RNase III-deficient *E. coli* strain as the micro-organism carrying a double-stranded RNA and T7 promoters.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because the use of RNase III-negative bacterial strain would prevent cleavage of T7 promoters and the double-stranded RNA molecule, as taught by Talkad et al. Since the RNase III-negative *E. coli* strain was known and available in the art at the time of the invention, and since replacing the BL21/DE3 *E. coli* strain with the RNase III-negative *E. coli* strain was within the technical grasp of one of ordinary skill in the art at the time of the invention, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635